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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/492,971	01/27/2000	Tikva Vogel	25775-C JPW/SJT	1611

7590 04/20/2005  
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New York, NY 10036

EXAMINER
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MITRA, RITA

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 04/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/492,971	<b>Applicant(s)</b> VOQEL ET AL.	
	<b>Examiner</b> Rita Mitra	<b>Art Unit</b> 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 88, 89 and 92-96 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 88, 89, 92-96 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ From the 8/13/10 4/20/11

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## **DETAILED ACTION**

### ***Status of the Claims***

Applicants' response to office action dated November 6, 2001, filed on May 13, 2002 is acknowledged. Claims 88 and 89 have been amended and entered. Claims 90 and 91 have been canceled. Therefore, claims 88, 89 and 92-96 are currently pending and are under examination. A substitute "Sequence Listing" and "CRF" filed on December 13, 2004 is acknowledged.

### ***Response to Remarks and Arguments***

#### **Maintenance of Rejections**

#### **Rejection under 35 U.S.C. 112, First Paragraph**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 88, 89 and 92-96 remain/are rejected under **35 U.S.C. 112, first paragraph**, because the specification, while being enabling for the fibronectin fragments disclosed in the specification, does not reasonably provide enablement for all portions of fibronectin. The specification does not enable a person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

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Applicants' arguments and remarks on page 3-10 have been fully considered but not found persuasive. Specification page 47, lines 10-15 defined the 31 kD polypeptide as corresponding to an amino acid sequence present in the fibrin binding domain (FBD) and having the amino acid sequence 1-262 (Fig 1) of full length FBD of human fibronectin, further at page 11, lines 14-19 the specification indicates that FBD commences at amino acid position 1 of mature fibronectin, which is glutamine and corresponds to the fourth amino acid (Q) shown in Fig 1a, i.e. the N-terminus of FBD sequence is QAQQ. If FBD is commencing at amino acid position 1, it cannot lead to a conclusion that the N-terminus of FBD sequence is QAQQ. Furthermore applicants argue that one of ordinary skill in the art would be able to readily calculate the one fifth of 262 amino acids corresponds to about 52 amino acids, however neither the specification nor the claim defines clearly the position of this one fifth portion in relation to the amino acid sequence of the FBD of naturally occurring fibronectin. Applicants remark on page 6, lines 1-18 is solely based on an extrapolation of the description at pages 11 and 47 of the specification and further linking with the limitation of amended claim 88. However, one of skill in the art would not have the same interpretation and would have required undue experimentation for one of skill in the art to determine all possible imaging agents derivable, having at least one fifth of the amino acid sequence of the N-terminal region from the fibrin binding domain of fibronectin. A large number of such polypeptides are easily envisioned but the determination of the biological activity of all such polypeptides would require undue experimentation because the purification, refolding and labeling of all such polypeptides is well outside the realm of routine experimental work. One of skill would require guidance, lacking in the specification, as to exactly what polypeptides might possess the claimed activity. One of skill would require guidance as to what region of fibronectin is included in the phrase the "fibrin binding domain", what specific amino acids does this encompass, and what is the sequence. It is *a priori* unknown and unpredictable as to which of the large number of polypeptides encompassed by the scope of these claims would have the claimed biological activity i.e. being capable of binding to fibrin. The mere fact that a polypeptide derived from or a fragment of a domain having fibrin binding activity not necessarily would also have fibrin binding activity. Therefore, one of skill would require guidance in order to make and use of the claimed polypeptides, without such guidance the experimentation left to those skilled in the art is undue.

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**Rejection under 35 U.S.C. 112, Second Paragraph**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

“The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.”

Claims 88, 89 and 92-96 remain/are rejected under **35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear from the amended claim 88 or the specification that what is the corresponding amino acid sequence, which comprises at least one-fifth portion of the amino acid sequence of the N-terminal region of the fibrin binding domain of fibronectin. Furthermore, claim recites “... and having the amino acid sequence gln-ala-gln-gln or met-gln-ala-gln-gln at the N-terminus of the polypeptide”. This renders the claim indefinite because it is not clear what is the one-fifth portion of the amino acids in relation to the recited sequences, are these the one-fifth or is it one-fifth of these sequences? The amino acid sequences have not been given a sequence identifier, which makes the claim indefinite as to which sequences are defined in the claims.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

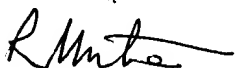
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***Conclusion***

No claims are allowed.

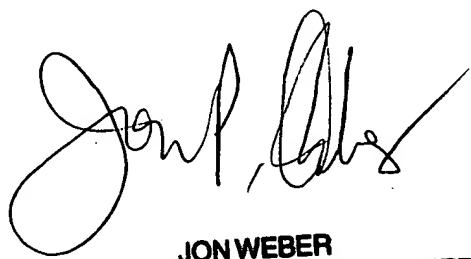
***Inquiries***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (571) 272-0954. The Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Jon Weber, can be reached at (571) 272-0925. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0547.



Rita Mitra, Ph.D.

April 12, 2005



**JON WEBER**  
**SUPERVISORY PATENT EXAMINER**